

REMARKS

This application has been reviewed in light of the Office Action dated February 1, 2010.

Claims 1-37 are in the application; claims 21-35 were withdrawn from consideration by the Examiner. Claims 1-20, 36 and 37 are now presented for examination. Claims 1, 6, 9, 11 and 13 have been amended. Claims 36 and 37 have been added. Claim 1 is the only remaining independent claim. Favorable review is respectfully requested.

Rejection under 35 U.S.C. §112

Claims 6 and 13 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner stated that the term "such as" rendered those claims indefinite. Claims 6 and 13 have been amended to remove "such as" and the recited examples. New claims 36 and 37 positively recite the examples from claims 6 and 13 respectively. It is earnestly believed that all of the claims are in compliance with 35 U.S.C. §112.

Claim amendments

Claim 1 is directed to a coated implant, comprising an implant having a pre-treated surface and one or more layers thereon of mainly non-hydrated chemically bonded ceramic material. Claim 1 has been amended to further recite that the implant is additionally coated with a ceramic paste; this ceramic paste coating comprises a powdered calcium-based binder of aluminate and/or silica and a hydration liquid. This added claim language is supported in the specification at least at page 2, line 11, and in originally filed claim 31, with reference to FIGS. 2 and 3.

Dependent claims 9 and 11 have been amended to conform more closely to the amended language of claim 1. In particular, claim 9 recites that the paste is in addition to the previously recited layers. With regard to claim 11, since the ceramic paste is an additional coating on the coated implant, the outermost layer is now recited as beneath the paste.

No new matter has been added.

Rejections under 35 U.S.C. §102

Claims 1-20 were rejected under 35 U.S.C. §102(b) or 35 U.S.C. §102(e) over five references, which are discussed separately below. The applicants respectfully submit that claim 1, as amended, is patentably distinct from the cited references. None of the cited references discloses or suggests an implant coated with one or more layers of a non-hydrated chemically bonded ceramic material, where the material is chemically and/or mechanically bound to the implant, and in particular where the implant additionally is coated with a ceramic paste.

Rejection under 35 U.S.C. §102(b): Cini et al.

Claims 1-5 and 14 were rejected under 35 U.S.C. §102(b) as anticipated by the Cini et al. article (J. Biomed. Mater. Res. 9, 441 (1975)). Cini et al. is understood to disclose ceramic implants that become hydrated after implantation in tissue. Cini et al. does not disclose or suggest pre-treating the implant surface, or coating the surface with a non-hydrated layer. (The Cini et al. implant material was precalcinated and humidified, but evidently there was no surface treatment after forming the implant.) Furthermore, the reference offers no teaching or suggestion regarding a ceramic paste coating the implant. The Cini et al. reference thus does not meet the limitations of independent claim 1.

Rejection under 35 U.S.C. §102(b): Borom

Claims 1-5, 7, 9, and 13-20 were rejected under 35 U.S.C. §102(b) as anticipated by Borom (U.S. Pat. No. 4,237,559). Borom is understood to disclose an implant where a first member 24 is coated with a second member 25. Borom discusses details of the coating (second member), but does not disclose or suggest that a surface of the first member is pretreated. Borom also does not disclose or suggest that the coating is mainly non-hydrated. Furthermore, the reference offers no teaching or suggestion regarding a ceramic paste coating the implant. Accordingly, this reference does not meet the limitations of claim 1.

Rejection under 35 U.S.C. §102(e): Axen et al. '903

Claims 1-20 were rejected under 35 U.S.C. §102(e) as anticipated by Axen et al. (U.S. Pat. Application Publication No. 2004/0247903) as evidenced by Cini et al. Axen et al. '903 is understood to disclose coatings for medical devices, including implants, where the substrate

surface is pretreated. The substrate is coated with calcium aluminate in a slurry, and the coating is then hardened. Axen et al. states that the hardening process is a hydration (paragraph 0063). This coating therefore is not a mainly non-hydrated chemically bonded ceramic, as recited in claim 1. Furthermore, neither reference offers any teaching or suggestion regarding a ceramic paste coating the implant. Accordingly, the Axen et al. '903 and Cini et al. references, considered either separately or in combination, do not meet the limitations of claim 1.

Rejection under 35 U.S.C. §102(b): Dunn et al.

Claims 1-7, 9, 13-15, and 18-20 were rejected under 35 U.S.C. §102(b) as anticipated by Dunn et al. (U.S. Pat. No. 4,655,777) as evidenced by Cini et al. Dunn et al. is understood to disclose an implant where the substrate is a polymer and is coated with a layer of ceramic fibers (col. 11, lines 39-50). The applicants wish to point out that Dunn et al. specifies that the ceramic fiber layers are laminated with the polymer, so that the top layer is polymer rather than ceramic. This arrangement is clearly distinct from claim 1, which recites that the coated implant additionally is coated with a ceramic paste. As noted above, Cini et al. likewise offers no teaching or suggestion regarding a ceramic paste coating the implant. Accordingly, the Dunn et al. and Cini et al. references, considered either separately or in combination, do not meet the limitations of claim 1.

Rejection under 35 U.S.C. §102(e): Axen et al. '484

Claims 1-20 were rejected under 35 U.S.C. §102(e) as anticipated by Axen et al. (U.S. Pat. Application Publication No. 2003/0215484). Axen et al. '484 is understood to disclose coated implants where the substrate is pretreated, and a powder containing ceramic material is applied to the substrate without a hydration process (paragraph 0023). In a subsequent step (paragraph 0031), hydration is performed on this powder layer. The coated implant of Axen et al. '484, when completed and prepared for in vivo-anchoring, thus has a hydrated ceramic material. This is contrary to the material layers recited in claim 1. Furthermore, the reference offers no teaching or suggestion regarding a ceramic paste coating the implant. Accordingly, this reference does not meet the limitations of claim 1.

Withdrawal of the 35 U.S.C. §102 rejections is therefore respectfully requested.

The applicants also wish to point out that a person skilled in the art, wishing to improve *in vivo* anchoring of a coated implant in hard tissue, would not be led by any of the references to a coated implant additionally coated with a ceramic paste, as recited in the claims. As explained in the specification (page 8, lines 22-25), the additional ceramic paste coating enables the coated implant to fill the gap between the implant and biological tissues, and filling vacuoles or cavities in the surface of neighboring bone tissue. The ceramic paste thereby improves anchoring of the implant to the bone tissue. In an embodiment, shown in FIGS. 2-5 of the specification, a vacuole is filled using a paste layer of an implant. In these figures, layer 5 is the paste and layer 4 is a hard tissue such as bone tissue. As shown in FIG. 3, the paste 5 is effective to fill the gap "X" and vacuole 6. This process is discussed in detail in the specification at page 10, line 31, to page 12, line 3. As shown in Table 3 on page 13 of the specification (comparing removal torque 24 hours after implantation of differently treated titanium screws), the highest removal torque was obtained with the screw which had been dipped in ceramic paste.

Since the cited references do not disclose or suggest any coated implant with the claimed features (particularly the additional coating of ceramic paste recited in claim 1), the claimed coated implant would not have been obvious from those references.

The other claims now pending in the application are dependent from the independent claim discussed above and are believed to be patentable for the same reasons. Since each dependent claim is directed to a separate aspect of the invention, however, the individual consideration of each claim on its own merits is respectfully requested.

In view of the foregoing amendments and remarks, favorable consideration and early passage to issue of the application are respectfully requested.

The applicants' undersigned attorney may be reached by telephone at 212-551-2625. All correspondence should continue to be directed to the address given below, which is the address associated with Customer Number 27267.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jay H. Anderson", with a long horizontal flourish extending to the right.

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